IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB MANUFACTURING IRELAND LIMITED, UCB PHARMA GMBH, and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. MYLAN TECHNOLOGIES, INC., MYLAN PHARMACEUTICALS, INC., and MYLAN INC., Defendants.	)	C.A. No. 1:17-cv-00322

MYLAN TECHNOLOGIES, INC, MYLAN PHARMACEUTICALS INC. AND MYLAN INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendants Mylan Technologies, Inc. ("MTI"), Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan"), by and through their counsel, hereby answer and respond to each of the allegations of the Complaint of Plaintiffs UCB, Inc., UCB Manufacturing Ireland Limited, UCB Pharma GMBH, and LTS Lohmann Therapie-Systeme AG (collectively, "Plaintiffs") (D.I. 1), and assert its separate defenses and counterclaims as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Mylan denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arises from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 209982 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendants seek approval to market generic versions of the pharmaceutical product Neupro® prior to the expiration of United States Patent Nos. 6,884,434 ("the '434 Patent"); 7,413,747

("the '747 Patent"); 8,246,979 ("the '979 Patent"); 8,246,980 ("the '980 Patent"); and 8,617,591 ("the '591 Patent"). Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Mylan admits that Plaintiffs purport to bring this action under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*. Mylan further admits that MTI filed ANDA No. 209982 seeking approval for rotigotine transdermal system, 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, 8 mg/24 hours prior to the expiration of the '434, '747, '979, '980, and '591 patents, and U.S. Patent No. 6,699,498 ("the '498 patent"). Mylan denies the allegations contained in paragraph 1 of the Complaint not expressly admitted.

PARTIES

2. Plaintiff UCB, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

ANSWER: Mylan lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 2 of the Complaint, and on that basis, denies them.

3. Plaintiff UCB Manufacturing Ireland Limited ("UCB Ireland") is a corporation organized and existing under the laws of Republic of Ireland, having an office and place of business at Shannon Industrial Estate, Shannon, Co. Clare, Ireland.

ANSWER: Mylan lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 3 of the Complaint, and on that basis, denies them.

4. Plaintiff UCB Pharma GmbH ("UCB Pharma") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Alfred Nobel Strasse 10, 40789 Monheim, Germany.

ANSWER: Mylan lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 4 of the Complaint, and on that basis, denies them.

5. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Lohmannstrasse 2, 56626 Andernach, Germany.

ANSWER: Mylan lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 5 of the Complaint, and on that basis, denies them.

6. Defendant MTI is a West Virginia corporation with a principal place of business at 110 Lake St., St. Albans, VT. Upon information and belief, MTI is a wholly-owned subsidiary of Mylan, Inc.

ANSWER: Admitted.

7. Defendant MPI is a West Virginia corporation with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. MPI maintains a registered agent in Delaware. MPI may be served with process in Delaware via the Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808. Upon information and belief, MPI is a wholly-owned subsidiary of Mylan, Inc.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Mylan admits that Mylan Pharmaceuticals Inc. ("MPI") is a wholly owned subsidiary of Mylan Inc. and it is a corporation organized and existing under the laws of West Virginia having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan denies the allegations contained in paragraph 7 of the Complaint not expressly admitted.

8. Defendant Mylan, Inc. is a Pennsylvania corporation with a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

ANSWER: Admitted.

JURISDICTION AND VENUE

9. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '434 Patent; the '747 Patent; the '979 Patent; the '980 Patent; and the '591 Patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Mylan admits that Plaintiffs purport to bring this action under the Patent Laws of the United States and the Food and Drug laws of the United States. Mylan denies that this Court has subject matter jurisdiction over allegations related to any alleged infringement under 35 U.S.C. §§ 271(a), (b), and/or (c). Mylan further denies that venue is proper in this district.

10. This Court has personal jurisdiction over MTI. On information and belief, MTI, directly or through its affiliates and agents, develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. On information and belief, upon receiving FDA approval, MTI intends to market and sell the proposed generic products at issue in this litigation, Rotigotine Transdermal System (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours) ("ANDA Products") throughout the United States, including in this judicial district. On information and belief, MTI has engaged in systematic and continuous contacts with the State of Delaware. MTI has registered pursuant to Del. Code. Ann. Tit. 24 § 2540 to distribute generic pharmaceutical products in Delaware and on information and belief holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy. MTI is accordingly "at home" in this judicial district.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Mylan denies that MTI is subject to personal jurisdiction in this Court. Mylan denies the allegations contained in paragraph 10 of the Complaint not expressly admitted.

11. This Court has jurisdiction over MPI. MPI has registered to do business in Delaware and maintains a registered agent in Delaware, and MPI may be served with process in Delaware via its registered agent, the Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808. Further, MPI has registered pursuant to Del. Code. Ann. Tit. 24 § 2540 to distribute generic pharmaceutical products in Delaware and on information and belief holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy. MPI has also availed itself of the protections of this Court as a plaintiff in this District. MPI is accordingly "at home" in this judicial district.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Mylan denies that MPI is subject to

personal jurisdiction in this Court. Mylan denies the allegations contained in paragraph 11 of the Complaint not expressly admitted.

12. This Court has jurisdiction over Mylan, Inc. Mylan, Inc, directly or through its affiliates and agents including its subsidiaries MTI and MPI, develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. On information and belief, upon receiving FDA approval, Mylan intends to market and sell the ANDA Products in this judicial district. On information and belief, Mylan, Inc., MPI, and MTI are agents of each other with respect to the development, regulatory approval, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Mylan denies that Mylan Inc. is subject to personal jurisdiction in this Court. Mylan denies the allegations contained in paragraph 12 of the Complaint not expressly admitted.

13. This Court further has jurisdiction because on information and belief, Mylan has purposefully availed itself of the privilege of doing business in Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States including the State of Delaware, and/or by selling, directly or through its agents, pharmaceutical products in the State of Delaware. Upon information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States including in Delaware.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Mylan denies that it is subject to personal jurisdiction in this Court. Mylan denies the allegations contained in paragraph 13 of the Complaint not expressly admitted.

14. On information and belief, MTI, MPI, and Mylan, Inc. work together and act as one entity in seeking FDA approval of ANDA No. 209982.

ANSWER: Mylan admits that MTI filed ANDA No. 209982 seeking approval for rotigotine transdermal system, 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, 8 mg/24 hours. Paragraph 14 otherwise contains legal conclusions and allegations

to which no answer is required. To the extent an answer is deemed required, Mylan denies the allegations contained in paragraph 14.

15. On information and belief, Mylan plans to market and sell purported generic versions of Neupro® in Delaware, list purported generic versions of Neupro® on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of purported generic versions of Neupro® in Delaware.

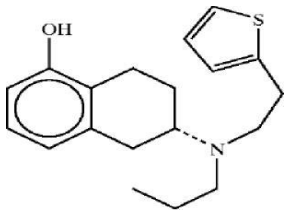
ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Mylan denies that it is subject to personal jurisdiction in this Court or that venue is proper. Mylan denies the allegations contained in paragraph 15 of the Complaint not expressly admitted.

PLAINTIFFS' PATENTS AND APPROVED NEUPRO® DRUG PRODUCT

16. Plaintiffs make and sell Neupro® (Rotigotine Transdermal System), a treatment for the signs and symptoms of idiopathic Parkinson's disease ("PD") and moderate-to-severe Restless Legs Syndrome ("RLS"). PD affects movement, producing motor symptoms such as tremor, slowed movement, rigidity, and postural instability. PD can also cause neuropsychiatric disturbances, including disorders of speech, cognition, mood, behavior, and thought. RLS is characterized by uncomfortable or odd sensations in a person's limbs, which cause an irresistible urge to move the body for temporary relief.

ANSWER: Mylan admits that Plaintiffs purport to make and sell products that are marketed under the trade name Neupro®, approved for treatment of Parkinson's disease and moderate-to-severe Restless Legs Syndrome. Mylan lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 16 of the Complaint, and on that basis, denies them.

17. Neupro® is the first FDA-approved product containing rotigotine, a synthetic dopamine agonist. In PD, neurodegeneration results in the loss of dopamine-producing neurons and reduced activity within certain dopaminergic pathways, and restoring activity to these systems with a dopamine agonist such as rotigotine may improve the clinical signs of PD. Rotigotine is also called (6S)-6-{propyl[2-(2-thienyl)ethyl]amino}-5,6,7,8-tetrahydro-1-naphthalenol; or (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol, and has the following formula:



ANSWER: Mylan lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 17 of the Complaint, and on that basis, denies them.

18. Neupro® is also the first FDA-approved transdermal treatment for PD. Neupro® is a transdermal system that provides continuous delivery of rotigotine for 24 hours following application to intact skin. The product is a thin, matrix-type transdermal system composed of three layers: a backing film, drug matrix, and protective liner. The liner protects the drug matrix during storage and is removed just prior to application. Neupro® is approved and marketed in six different strengths: 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours and 8 mg/24 hours.

ANSWER: Mylan admits that the products that are the subject of NDA No. 021829 are marketed under the trade name Neupro®, approved in six different strengths: 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours and 8 mg/24 hours. Mylan lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 18 of the Complaint, and on that basis, denies them.

19. Neupro®'s transdermal delivery of rotigotine has been shown to provide stable plasma levels of rotigotine over 24 hours, which may prevent or reduce long-term motor complications and motor fluctuations that are associated with unstable or fluctuating dopaminergic stimulation. Neupro® also offers other advantages. For example, by delivering drug via transdermal application, Neupro® bypasses gastrointestinal complications that may be associated with PD. In addition, Neupro®'s once-daily formulation for 24 hours of treatment may improve early morning and nighttime symptoms of PD, as well as patient compliance.

ANSWER: Mylan lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 19 of the Complaint, and on that basis, denies them.

20. Plaintiff UCB, Inc. is the holder of New Drug Application ("NDA") No. 021829 for Neupro® (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and

8 mg/24 hours). FDA initially approved NDA No. 021829 in May 2007, for the treatment of signs and symptoms of early stage idiopathic PD. Following manufacturing and process changes to address product stability, and following additional clinical trials, in April 2012, FDA approved a new formulation of Neupro® for additional indications, i.e., for the treatment of the signs and symptoms of advanced stage idiopathic PD, and for the treatment for moderate-to-severe RLS. In its April 2012 approval of Neupro®, FDA granted Neupro® three years of regulatory exclusivity pursuant to 21 C.F.R. 314.108.

ANSWER: Mylan admits that the products that are the subject of NDA No. 021829 are marketed under the trade name Neupro®. Mylan admits that UCB, Inc. is indicated in the records of the FDA as the holder of NDA No. 021829 for rotigotine transdermal formulations (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours). Mylan lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 20 of the Complaint, and on that basis, denies them.

21. The ’434, ’747, ’979, ’980, and ’591 Patents are listed in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for Neupro®.

ANSWER: Admitted.

22. On April 26, 2005, the USPTO duly and lawfully issued the ’434 Patent, entitled “Transdermal Therapeutic System Which Contains a D2 Agonist and Which is Provided for Treating Parkinsonism, and a Method for the Production Thereof.” A true and correct copy of the ’434 Patent is attached as Exhibit A.

ANSWER: Mylan admits that Plaintiffs purport to attach a copy of the ’434 patent to the Complaint as Exhibit A. Mylan further admits that on its face, the ’434 patent is titled “Transdermal Therapeutic System Which Contains a D2 Agonist and Which is Provided for Treating Parkinsonism, and a Method for the Production Thereof,” and indicates that it issued on April 26, 2005. Mylan denies the remaining allegations of paragraph 22, including any suggestion or implication that the ’434 patent was duly and legally issued or is valid or enforceable.

23. On August 19, 2008, the USPTO duly and lawfully issued the '747 Patent, entitled "Transdermal Therapeutic System for Treating Parkinsonism." A true and correct copy of the '747 Patent is attached as Exhibit B.

ANSWER: Mylan admits that Plaintiffs purport to attach a copy of the '747 patent to the Complaint as Exhibit B. Mylan further admits that on its face, the '747 patent is titled "Transdermal Therapeutic System for Treating Parkinsonism," and indicates that it issued on August 19, 2008. Mylan denies the remaining allegations of paragraph 23, including any suggestion or implication that the '747 patent was duly and legally issued or is valid or enforceable.

24. On August 21, 2012, the USPTO duly and lawfully issued the '979 Patent, entitled "Transdermal Delivery System for the Administration of Rotigotine." A true and correct copy of the '979 Patent is attached as Exhibit C.

ANSWER: Mylan admits that Plaintiffs purport to attach a copy of the '979 patent to the Complaint as Exhibit C. Mylan further admits that on its face, the '979 patent is titled "Transdermal Delivery System for the Administration of Rotigotine," and indicates that it issued on August 21, 2012. Mylan denies the remaining allegations of paragraph 24, including any suggestion or implication that the '979 patent was duly and legally issued or is valid or enforceable.

25. On August 21, 2012, the USPTO duly and lawfully issued the '980 Patent, entitled "Transdermal Delivery System." A true and correct copy of the '980 Patent is attached as Exhibit D.

ANSWER: Mylan admits that Plaintiffs purport to attach a copy of the '980 patent to the Complaint as Exhibit D. Mylan further admits that on its face, the '980 patent is titled "Transdermal Delivery System," and indicates that it issued on August 21, 2012. Mylan denies the remaining allegations of paragraph 25, including any suggestion or implication that the '980 patent was duly and legally issued or is valid or enforceable.

26. On December 31, 2013, the USPTO duly and lawfully issued the '591 Patent, entitled "Transdermal Delivery System for the Administration of Rotigotine." A true and correct copy of the '591 Patent is attached as Exhibit E.

ANSWER: Mylan admits that Plaintiffs purport to attach a copy of the '591 patent to the Complaint as Exhibit E. Mylan further admits that on its face, the '591 patent is titled "Transdermal Delivery System for the Administration of Rotigotine," and indicates that it issued on December 31, 2013. Mylan denies the remaining allegations of paragraph 26, including any suggestion or implication that the '591 patent was duly and legally issued or is valid or enforceable.

27. Each of the '434, '747, '979, '980, and '591 Patents is owned or co-owned by one or more of Plaintiffs UCB Ireland, UCB Pharma, and LTS.

ANSWER: Mylan admits that the USPTO's electronic assignment database indicates that each of the '434, '747, '979, '980, and '591 Patents is owned or co-owned by one or more of Plaintiffs UCB Ireland, UCB Pharma, and LTS. Mylan denies the allegations contained in paragraph 27 of the Complaint not expressly admitted.

THE MYLAN ANDA

28. On information and belief, Mylan submitted or caused to be submitted ANDA No. 209982 ("the Mylan ANDA") to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of Rotigotine Transdermal System (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours) ("ANDA Products"), as purported generic versions of Neupro®, prior to the expiration of the '979, '980, '591, '747, and '434 Patents.

ANSWER: Mylan admits that MTI filed ANDA No. 209982 seeking approval for Rotigotine Transdermal System (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours) prior to the expiration of the'979, '980, '591, '747, and '434 Patents. Mylan denies the allegations contained in paragraph 28 of the Complaint not expressly admitted.

29. On information and belief, on or about February 27, 2017, Defendant MTI sent Plaintiffs a letter purporting to provide notice of certification concerning the '434, '747, '979, '980, and '591 Patents pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act and 21 C.P.R. §§ 314.94 and 314.95. (the "Notice Letter"). The Notice Letter further represented that MTI had submitted to FDA a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Mylan ANDA before the expiration of the patents listed in the Orange Book for NDA No. 021829. Hence, Mylan's purpose in submitting its ANDA is to manufacture and market the ANDA Products before the expiration of the'434, '747. '979, '980, and '591 Patents. The Notice Letter also stated that the Paragraph IV certification alleges that the '434, '747, '979, '980, and '591 Patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

ANSWER: Mylan admits that MTI provided notice to Plaintiffs by letter dated February 27, 2017, of a certification concerning the '498, '434, '747, '979, '980, and '591 Patents pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act and 21 C.P.R. §§ 314.94 and 314.95, that the claims of the '498, '434, '747, '979, '980, and '591 Patents are invalid, unenforceable, and/or not infringed. Mylan admits that MTI provided notice to Plaintiffs by letter dated February 27, 2017, that it had submitted to FDA a Paragraph IV certification to obtain approval before the expiration of the patents listed in the Orange Book for NDA No. 021829. Mylan denies the allegations contained in paragraph 29 of the Complaint not expressly admitted.

30. On information and belief, MPI and Mylan, Inc. have assisted with and participated in the preparation and submission of the Mylan ANDA and the development of the ANDA Products, have provided material support to the preparation and submission of the Mylan ANDA, and have supported prosecution of the Mylan ANDA.

ANSWER: Mylan admits that MTI filed ANDA No. 209982. Mylan denies the allegations contained in paragraph 30 of the Complaint not expressly admitted.

31. On information and belief, if FDA approves the Mylan ANDA, Mylan will manufacture, offer for sale, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States.

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent and answer is required, denied.

32. On information and belief, if FDA approves the Mylan ANDA, Mylan will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent and answer is required, denied.

33. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the Notice Letter.

ANSWER: Admitted.

COUNT I: CLAIM FOR INFRINGEMENT OF THE '434 PATENT

34. Plaintiffs restate, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Mylan incorporates its Answer to paragraphs 1-33 as if fully set forth herein.

35. On information and belief, Defendants submitted or caused the submission of the Mylan ANDA to FDA, and continue to seek FDA approval of the Mylan ANDA.

ANSWER: Mylan admits that MTI filed ANDA No. 209982 seeking approval for rotigotine transdermal system, 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, 8 mg/24 hours. Mylan denies the allegations contained in paragraph 35 of the Complaint not expressly admitted.

36. Defendants have infringed the '434 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '434 Patent. In the Notice Letter, MTI has not asserted non-infringement of claims 1-3, 5, 7, and 14-15 of the '434 Patent.

ANSWER: Denied.

37. Mylan's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '434 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209982, Mylan will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and

will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '434 Patent.

ANSWER: Denied.

38. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using and applying the ANDA Products. Accordingly, Mylan will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '434 Patent. In addition, on information and belief, Mylan will encourage acts of direct infringement with knowledge of the '434 Patent and knowledge that they are encouraging infringement

ANSWER: Denied.

39. Defendants had knowledge of the '434 Patent prior to filing the Mylan ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '434 Patent would constitute an act of infringement of the '434 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '434 Patent. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the '434 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity and non-infringement with respect to the '434 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

ANSWER: Denied.

40. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '434 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '747 PATENT

41. Plaintiffs restate, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Mylan incorporates its Answer to paragraphs 1-40 as if fully set forth herein.

42. On information and belief, Defendants submitted or caused the submission of the Mylan ANDA to FDA, and continue to seek FDA approval of the Mylan ANDA.

ANSWER: Mylan admits that MTI filed ANDA No. 209982 seeking approval for rotigotine transdermal system, 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, 8 mg/24 hours. Mylan denies the allegations contained in paragraph 42 of the Complaint not expressly admitted.

43. Defendants have infringed the '747 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '747 Patent. In the Notice Letter, MTI has not asserted non-infringement of claims 1-6, 8-11, and 13 of the '747 Patent.

ANSWER: Denied.

44. Mylan's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '747 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209982, Mylan will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '747 Patent.

ANSWER: Denied.

45. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using and applying the ANDA Products. Accordingly, Mylan will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '747 Patent. In addition, on information and belief, Mylan will encourage acts of direct infringement with knowledge of the '747 Patent and knowledge that they are encouraging infringement.

ANSWER: Denied.

46. Defendants had knowledge of the '747 Patent prior to filing the Mylan ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '747 Patent would constitute an act of infringement of the '747 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '747 Patent. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the '747 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products.

Defendants' conduct in certifying invalidity and non-infringement with respect to the '747 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

ANSWER: Denied.

47. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '747 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

COUNT III: CLAIM FOR INFRINGEMENT OF THE '979 PATENT

48. Plaintiffs restate, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Mylan incorporates its Answer to paragraphs 1-47 as if fully set forth herein.

49. On information and belief, Defendants have submitted or caused the submission of the Mylan ANDA to FDA, and continue to seek FDA approval of the Mylan ANDA.

ANSWER: Mylan admits that MTI filed ANDA No. 209982 seeking approval for rotigotine transdermal system, 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, 8 mg/24 hours. Mylan denies the allegations contained in paragraph 49 of the Complaint not expressly admitted.

50. Defendants have infringed the '979 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '979 Patent. In the Notice Letter, Mylan has not asserted non-infringement of claims 1-5 or claims 7-18 of the '979 Patent.

ANSWER: Denied.

51. Mylan's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '979 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209982, Mylan will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '979 Patent.

ANSWER: Denied.

52. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using and applying the ANDA Products. Accordingly, Mylan will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '979 Patent. In addition, on information and belief, Mylan will encourage acts of direct infringement with knowledge of the '979 Patent and knowledge that they are encouraging infringement.

ANSWER: Denied.

53. Mylan had knowledge of the '979 Patent prior to filing the Mylan ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '979 Patent would constitute an act of infringement of the '979 Patent. Mylan had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '979 Patent. In addition, Mylan filed its ANDA without adequate justification for asserting the '979 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Mylan's conduct in certifying invalidity and non-infringement with respect to the '979 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

ANSWER: Denied.

54. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '979 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

COUNT IV: CLAIM FOR INFRINGEMENT OF THE '980 PATENT

55. Plaintiffs restate, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Mylan incorporates its Answer to paragraphs 1-54 as if fully set forth herein.

56. On information and belief, Defendants have submitted or caused the submission of the Mylan ANDA to FDA, and continue to seek FDA approval of the Mylan ANDA.

ANSWER: Mylan admits that MTI filed ANDA No. 209982 seeking approval for rotigotine transdermal system, 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6

mg/24 hours, 8 mg/24 hours. Mylan denies the allegations contained in paragraph 56 of the Complaint not expressly admitted.

57. Defendants have infringed the '980 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '980 Patent. In the Notice Letter, MTI has not asserted non-infringement of claim 17 of the '980 Patent.

ANSWER: Denied.

58. Mylan's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '980 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209982, Mylan will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '980 Patent.

ANSWER: Denied.

59. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using and applying the ANDA Products. Accordingly, Mylan will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '980 Patent. In addition, on information and belief, Mylan will encourage acts of direct infringement with knowledge of the '980 Patent and knowledge that they are encouraging infringement.

ANSWER: Denied.

60. Defendants had knowledge of the '980 Patent prior to filing the Mylan ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '980 Patent would constitute an act of infringement of the '980 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '980 Patent. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the '980 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity and non-infringement with respect to the '980 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

ANSWER: Denied.

61. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '980 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

COUNT V: CLAIM FOR INFRINGEMENT OF THE '591 PATENT

62. Plaintiffs restate, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: Mylan incorporates its Answer to paragraphs 1-61 as if fully set forth herein.

63. On information and belief, Defendants have submitted or caused the submission of the Mylan ANDA to FDA, and continue to seek FDA approval of the Mylan ANDA.

ANSWER: Mylan admits that MTI filed ANDA No. 209982 seeking approval for rotigotine transdermal system, 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, 8 mg/24 hours. Mylan denies the allegations contained in paragraph 63 of the Complaint not expressly admitted.

64. Defendants have infringed the '591 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '591 Patent. In the Notice Letter, MTI has not asserted non-infringement of claims 1-3, 6-17, or 20-30 of the '591 Patent.

ANSWER: Denied.

65. Mylan's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '591 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209982, Mylan will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '591 Patent.

ANSWER: Denied.

66. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for

using and applying the ANDA Products. Accordingly, Mylan will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '591 Patent. In addition, on information and belief, Mylan will encourage acts of direct infringement with knowledge of the '591 Patent and knowledge that they are encouraging infringement.

ANSWER: Denied.

67. Defendants had knowledge of the '591 Patent prior to filing the Mylan ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '591 Patent would constitute an act of infringement of the '591 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '591 Patent. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the '591 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity and non-infringement with respect to the '591 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

ANSWER: Denied.

68. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '591 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

PRAYER FOR RELIEF

All remaining allegations not specifically admitted are herein denied. It is further denied that Plaintiffs are entitled to the relief requested in the Complaint or to any other relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Mylan asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs.

FIRST SEPARATE DEFENSE

Mylan is not subject to personal jurisdiction in the District of Delaware. Plaintiffs do not and cannot establish that sufficient grounds exist, under the applicable constitutional standards or long-arm statute, for this Court to exercise personal jurisdiction over Mylan in this action.

SECOND SEPARATE DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. § 271(a), (b), and/or (c) against Mylan because Plaintiffs have not pleaded with particularity facts regarding any post-ANDA approval activities.

THIRD SEPARATE DEFENSE

Venue is improper in the District of Delaware.

FOURTH SEPARATE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

FIFTH SEPARATE DEFENSE

The claims of the ’434, ’747, ’979, ’980, and ’591 patents are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting at least for the reasons set forth in the Detailed Statement of the factual and legal bases included with MTI’s February 27, 2017 notice letter to Plaintiffs.

SIXTH SEPARATE DEFENSE

Mylan has not directly or indirectly infringed any claims of the ’434, ’747, ’979, ’980, and ’591 patents. The filing of MTI’s ANDA No. 209982, and the manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of MTI’s ANDA No. 209982 does not and would not infringe any valid or enforceable claim of the ’434, ’747, ’979, ’980, and ’591 patents, either literally or under the doctrine of equivalents.

SEVENTH SEPARATE DEFENSE

Mylan reserves all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case.

COUNTERCLAIMS

For its counterclaims against UCB, Inc., UCB Manufacturing Ireland Limited, UCB Pharma GmbH, and LTS Lohmann Teherapie-Systeme AG, (collectively "Counterclaim Defendants"), Mylan Technologies Inc. ("MTI") states as follows:

PARTIES

1. MTI is a West Virginia corporation with a principal place of business at 110 Lake St., St. Albans, VT.

2. Upon information and belief, UCB, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

3. Upon information and belief, UCB Manufacturing Ireland Limited ("UCB Ireland") is a corporation organized and existing under the laws of Republic of Ireland, having an office and place of business at Shannon Industrial Estate, Shannon, Co. Clare, Ireland.

4. Upon information and belief, UCB Pharma GmbH ("UCB Pharma") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Alfred Nobel Strasse 10, 40789 Monheim, Germany.

5. Upon information and belief, LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Lohmannstrasse 2, 56626 Andernach, Germany.

JURISDICTION AND VENUE

6. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. The Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants commenced and continue to maintain this action against MTI in this judicial district.

9. Venue is proper as to the Counterclaim Defendants pursuant to 28 U.S.C. §§ 1391(b) and (c) because Counterclaim Defendants have consented to venue in this Court by filing the instant action in this judicial district.

FACTUAL BACKGROUND

10. Upon information and belief, on March 2, 2004, the USPTO issued U.S. Patent No. 6,699,498 ("the '498 patent"), entitled "Transdermal Therapeutic Systems Having Improved Stability and Their Production." Upon information and belief, LTS is identified as the assignee of the '498 patent on its face. A copy of the '498 patent is attached hereto as Exhibit A.

11. Upon information and belief, UCB, Inc. is indicated in the records of the FDA as the holder of NDA No. 021829 for Neupro® rotigotine transdermal formulations (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours).

12. The '498 patent, as well as U.S. Patent Nos. 6,884,434 ("the '434 patent"), 7,413,747 ("the '747 patent"), 8,246,979 ("the '979 patent"), 8,246,980 ("the '980 patent"), and 8,617,591 ("the '591 patent") are listed in the electronic version of the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Neupro®.

13. MTI filed ANDA No. 209982 seeking approval from the FDA for its rotigotine transdermal formulations (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours).

14. By letter dated February 27, 2017 ("MTI's Notice Letter"), MTI notified Counterclaim Defendants in writing that it had filed ANDA No. 209982 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '498, '434, '747, '979, '980, and '591 patents are invalid, unenforceable, and/or will not be infringed by the products that are the subject of ANDA No. 209982.

15. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), MTI's Notice Letter was accompanied by a detailed statement of the factual and legal bases for MTI's Paragraph IV Certification that the '498, '434, '747, '979, '980, and '591 patents are invalid, unenforceable, and/or will not be infringed.

16. On March 24, 2017, Counterclaim Defendants filed an action against MTI for infringement of the '434, '747, '979, '980, and '591 patents. Counterclaim Defendants did not sue MTI for infringement of the '498 patent.

17. On information and belief, MTI is not a first filer eligible for exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv) with respect to the '498 patent. On information and belief, another party is a first filer eligible for exclusivity. On information and belief, the first filer has not forfeited exclusivity. That exclusivity would block MTI's ability to obtain final FDA approval of its ANDA product.

DECLARATORY JUDGMENT

COUNT 1: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '498 PATENT

18. MTI repeats and realleges the allegations in paragraphs 1-17 of its counterclaims as if fully set forth herein.

19. More than forty-five days have elapsed since Counterclaim Defendants' receipt of MTI's Notice Letter.

20. To date, and upon information and belief, Counterclaim Defendants have not sued MTI for infringement of the '498 patent.

21. MTI denies infringement of the '498 patent and alleges that the manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of MTI's ANDA No. 209982 does not and will not infringe, nor contribute to or induce infringement of, any valid or enforceable claim of the '498 patent, either literally or under the doctrine of equivalents, for at least the reasons set forth by MTI in its Notice Letter.

22. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between the parties regarding the infringement of the '498 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

23. MTI is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of MTI's ANDA No. 209982 does not and will not infringe, nor contribute to or induce infringement of, any valid or enforceable claim of the '498 patent, either literally or under the doctrine of equivalents.

COUNT 2: DECLARATORY JUDGMENT OF INVALIDITY OF THE '498 PATENT

24. MTI repeats and realleges the allegations in paragraphs 1-23 of its counterclaims as if fully set forth herein.

25. More than forty-five days have elapsed since Counterclaim Defendants' receipt of MTI's Notice Letter.

26. To date, and upon information and belief, Counterclaim Defendants have not sued MTI for infringement of the '498 patent.

27. The claims of the '498 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the United States Patent Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

28. By way of example and not limitation, the claims of the '498 patent are invalid as obvious under 35 U.S.C. § 103 over the prior art, including at least one or more of the following references: PCT Publication No. WO 97/29735; U.S. Patent No. 5,807,570; J.P. Ostendorf, Measurement and Prevention of Oxidative Deterioration in Cosmetics and Pharmaceuticals, 16 J. Soc. Cosmetic Chemists 203-220 (1965); European Patent No. EP 0492930; and U.S. Patent No. 5,989,586.

29. By further way of example and not limitation, the claims of the '498 patent are invalid under 35 U.S.C. § 112 for failure to comply with the definiteness requirement. The claims of the '498 patent do not satisfy the definiteness requirement at least because they fail to inform with reasonable certainty those skilled in the art about the scope of the claimed invention.

30. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between the parties regarding the invalidity of the '498 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

31. MTI is entitled to a judicial declaration that the claims of the '498 patent are invalid.

PRAYER FOR RELEIF

WHEREFORE, MTI respectfully requests entry of judgment in its favor and against Counterclaim Defendants providing the following relief:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of ANDA No. 209982 has not infringed, does not infringe and would not infringe any valid or enforceable claim of the '498 patent, either literally or under the doctrine of equivalents;

(b) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of ANDA No. 209982 has not infringed, does not infringe and would not induce the infringement of any valid or enforceable claim of the '498 patent;

(c) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of ANDA No. 209982 has not infringed, does not infringe and would not contributorily infringe any valid or enforceable claim of the '498 patent;

(d) Declaring that the claims of the '498 patent are invalid;

(e) Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of MTI;

(f) Declaring this case exceptional and awarding Mylan its reasonable attorney's fees and costs pursuant to 35 U.S.C. § 285; and

(g) Awarding Mylan such other and further relief as the Court may deem just and proper.

Date: April 19, 2017

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